BIOCEPT INC

FORM 8-K
(Current report filing)

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Address	5810 NANCY RIDGE DR
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Telephone	858-320-8200
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Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 9, 2017

BIOCEPT, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36284**	**80-0943522**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

5810 Nancy Ridge Drive, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 320-8200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On February 9, 2017, Biocept, Inc. (the " ***Company*** ") issued a press release highlighting the Company's key accomplishments in 2016 and outlining the Company's anticipated value drivers for 2017. The full text of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release of Biocept, Inc. dated February 9, 2017.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOCEPT, INC.

Dated: February 9, 2017

By: /s/ Michael W. Nall
Name: Michael W. Nall
Title: President and Chief Executive Officer

Exhibit 99.1

Biocept's CEO Issues Letter to Stockholders

Highlights key accomplishments and outlines value drivers for 2017

SAN DIEGO (February 9, 2017) -- Biocept, Inc. (NASDAQ:BIOC), a leading commercial provider of liquid biopsy tests designed to provide physicians with clinically actionable information to improve the outcomes of cancer patients, announces that President and CEO Michael W. Nall has issued the following letter to stockholders:

To Our Stockholders and Friends:

The entire team at Biocept looks forward to 2017, as we work to advance our position as a commercial leader in liquid biopsy. The past year was eventful as we introduced new high-value biomarker assays, signed in-network provider agreements with major health plans, and reported positive clinical study results that further validate our Target Selector™ platform. It was gratifying to see these accomplishments reflected in our improved operational and financial performance, with strong year-over-year growth in sample volumes and the achievement of our first million-dollar quarter in the third quarter of 2016.

Among our notable achievements, we commercialized our liquid biopsy test for PD-L1 protein expression last June. The determination of PD-L1 status is necessary to qualify patients for certain targeted immuno-oncology therapeutics. This test was well received by the medical community and physician demand has been strong since its launch. The quantification of protein expression for tests like PD-L1 is performed on circulating tumor cells (CTCs) and cannot be determined from circulating tumor DNA (ctDNA). This is an example of how our Target Selector™ dual-platform, which analyzes cancer biomarkers found on CTCs and in ctDNA, can provide a more comprehensive answer than other liquid biopsy tests that only analyze ctDNA.

We started 2017 by announcing an in-network agreement with the largest health plan in Texas. This is a significant milestone for Biocept, as Texas is one of our largest markets. Today, I am pleased to report that we also recently entered into a group-purchasing agreement with a large, national health plan association. This agreement substantially increases the opportunity for Biocept to enter into additional in-network agreements with member plans throughout this network. The selection of our liquid biopsy offering resulted from a rigorous RFP process conducted by the health plan association, and establishes pricing for member plans that wish to contract with Biocept.

We also began 2017 with improvements in billing and collections as a result of the numerous actions we've taken to improve this aspect of our business. This effort is led by our CFO and Senior Vice President of Operations Tim Kennedy, who joined us last July and brings significant experience in this function. Tim and his team continue to make strides in streamlining our billing and operating procedures.

This year we expect to deliver on another significant milestone in the accounting function with our anticipated transition to accrual accounting, rather than our current method of reporting revenue on a cash basis. Accrual accounting will allow us to record revenues as our tests are performed, thereby providing for a more timely reflection of revenue associated with our test volume, and better alignment of revenues and expenses.

I'm pleased to share our priorities for 2017, which are aimed at growing our customer base, driving test volumes, and further building our leadership position.

These include:

- increasing the number of physicians ordering our liquid biopsy tests and expanding test volumes from our current base of accounts;
- signing additional health plan agreements to support third-party reimbursement for our tests;

- collaborating with top-tier oncology institutions to expand the commercial adoption of our liquid biopsy platform, and to conduct clinical studies that further validate the use of our tests;
- broadening our test menu with the introduction of new clinically actionable oncology biomarker assays; and
- forming partnerships in the U.S. and overseas to expand the distribution of our tests.

We look forward to reporting our progress on these priorities throughout the year.

We are optimistic about our future for numerous reasons including that we are an established player in a market that Wall Street analysts' project to exceed $10 billion by 2025. Our liquid biopsy tests are aligned with today's healthcare environment in which practitioners and providers seek to improve patient outcomes while reducing the cost of care. Compared with invasive tissue biopsies, our tests provide a non-invasive, cost-effective and accurate means of detecting and monitoring oncology biomarkers with the use of a simple blood sample. Clinical studies continue to validate our technology for high clinical sensitivity and concordance with tissue biopsy.

Importantly, there are four key areas of our business that we believe provide Biocept with a sustainable competitive advantage in the liquid biopsy market.

- First, our Target Selector™ dual-platform features a comprehensive menu of assays focused only on clinically validated cancer biomarkers, which is key to oncologists and their patients for tumor profiling and cancer monitoring. This menu uniquely includes tests for oncogenic mutations, gene fusions, amplifications, translocations, and proteins.
- Second, our CTC and ctDNA platforms leverage our proprietary biomarker enrichment technologies, resulting in industry-leading test performance.
- Third, our liquid biopsy solutions are cost-effective given their application in clinically actionable situations and their alignment with payer reimbursement policies. This increases the efficiency of our claims collections and assists in expanding the in-network coverage of Target Selector™ with major health plans that reimburse based on clinical utility, medical necessity, and cost.
- And lastly, our technologies are amenable to the development of Target Selector™ in vitro diagnostic (IVD) kits, allowing our liquid biopsy tests to be performed in laboratories around the world.

Later this year, we plan to initiate a commercial pilot program that will enable hospital-based pathologists to interpret the results of our liquid biopsy tests locally. This strategy is anticipated to increase the uptake of our novel testing platform by engaging molecular pathologists in hospital systems across the country. We also plan to initiate a clinical study for our Target Selector™ microchannel technology, which is the first step toward the development of our IVD kits. Our kit strategy will take time to develop and launch, given the requirement to conduct a clinical trial and obtain the necessary regulatory approvals. Nevertheless, by developing IVD kits based on our Target Selector™ technology, there is an opportunity to substantially leverage our liquid biopsy brand and expand our test volumes, our sales, and our operating margins in the future.

In closing, we have set forth a pathway to build on our many accomplishments, and seek to deliver additional value to patients, customers and our shareholders in 2017. On behalf of my colleagues, our Board, and our advisors, thank you for your continued support of Biocept.

Sincerely,

Michael W. Nall
President and Chief Executive Officer

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary liquid biopsy technology to provide physicians with information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both

circulating tumor cells (CTCs) and in circulating tumor DNA (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. For additional information, please visit www.biocept.com .

Forward-Looking Statements Disclaimer Statement

This release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to have been correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this release are not strictly historical, including without limitation statements as to our ability to improve the diagnosis and treatment of cancer, our ability to advance our position as a commercial leader in liquid biopsy, our ability to increase physician demand for our tests, our ability to transition to accrual accounting in 2017, our ability to implement our priorities in 2017 and their ability to grow our customer base, drive test volume and build our leadership position, the anticipated commercial opportunity of the liquid biopsy market, our ability to develop our IVD kit business, and our ability to enter into clinical studies to further validate the use of our tests, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risk factors as set forth in our Securities and Exchange Commission (SEC) filings. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC, which can be accessed over the Internet at the SEC's website located at www.sec.gov .

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